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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/537,102	06/02/2005	Juha Kuja-Panula	0933-0246PUS1	2142
2292	7590	04/05/2007	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH			WANG, CHANG YU	
PO BOX 747				
FALLS CHURCH, VA 22040-0747			ART UNIT	PAPER NUMBER
			1649	
SHORTENED STATUTORY PERIOD OF RESPONSE		NOTIFICATION DATE		DELIVERY MODE
3 MONTHS		04/05/2007		ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)
	10/537,102	KUJA-PANULA ET AL.
	Examiner	Art Unit
	Chang-Yu Wang	1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 1/8/07.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-61 is/are pending in the application.
 - 4a) Of the above claim(s) 1-6, 8-19, 21-57, 59-61 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 7,20 and 58 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 02 June 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date 6/2/05.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application
- 6) Other: _____.

DETAILED ACTION

Status of Application Election/Restrictions

Applicant's election with traverse of Group II (claims 7, 20, and 58) in the reply filed on January 8, 2007 is acknowledged. The traversal is on the ground(s) that Groups I and II are related subject matter. This is not found persuasive because DNA and proteins differ with respect to their compositions and structures and have different uses. In addition, the instant application does not have a single inventive concept and Groups I-II are directed to different technical features. Group I is directed to a technical feature of DNA and Group II is directed to a technical feature of protein, which is a different technical feature from that of Group I. Thus, the instant application lacks unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-61 are pending. During a telephone conversation with Dr. Thomas M. Siepmann on January 23, 2007, a provisional species election on SEQ ID NO:2 was made with traverse to prosecute the invention of Group II, claims 7, 20 and 58. Affirmation of this election must be made by Applicant in replying to this Office action. Claims 1-6, 8-19, 21-57, 59-61 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, there being no allowable generic or linking claim.

Claims 7, 20 and 58 are under examination in this office action.

Information Disclosure Statement

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Objections

Claims 7, 20 and 58 are objected to as encompassing non-elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20 and 58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

"There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy

the enablement requirement and whether any necessary experimentation is 'undue'. These factors include, but are not limited to:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention

based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)". See MPEP § 2164.01.

Claim 20 is directed to a pharmaceutical composition comprising the AMIGO polypeptide/peptide/fusion protein. Claim 58 is directed to a polypeptide comprising a fragment of an AMIGO that binds to an AMIGO receptor for the treatment of disease characterized by aberrant growth, migration, regeneration or proliferation that express an AMIGO receptor. Applicant shows that the extracellular domain of AMIGO immobilized on the culture plates can promote neurite outgrowth of cultured hippocampal neurons when neurons are grown on the plates coated with the extracellular domain of AMIGO. The neurite outgrowth of cultured hippocampal neurons can be inhibited by the soluble form of the extracellular domain of AMIGO in the medium. Applicant also shows that the

soluble form of the extracellular domain of AMIGO perturbs development of axonal fasciculation in cultured hippocampal neurons. Applicant shows that AMIGO can bind to EGFR and inhibit EGFR autophosphorylation. In addition, AMIGO has ability of homo- and heterophilic binding to AMIGO, AMIGO2 and AMIGO3.

Based on the specification, Applicant is enabled for enhancing neurite outgrowth of hippocampal neurons that are cultured on the plates coated with the extracellular domain of AMIGO. However, claim 20 is directed to a pharmaceutical composition comprising the AMIGO protein, peptide and fusion protein and claim 58 is directed to a polypeptide comprising a fragment that binds to an AMIGO receptor for treating diseases of aberrant growth. Applicant fails to provide sufficient guidance as to how to use the claimed pharmaceutical composition in treating all different diseases including different neurodegenerative diseases and neurological conditions that have different causes as described in the specification (see p. 47 & 49) since the soluble form of the ectodomain of AMIGO has inhibitory effects on neurite outgrowth and fasciculation. Applicant provides no guidance as to how to immobilize the full length or all fragments of AMIGO that could enhance neurite outgrowth in vivo to treat all neurological diseases since the soluble form of the ectodomain of AMIGO has inhibitory effects on neurite outgrowth and fasciculation. In addition, Applicant fails to provide sufficient guidance as to how to use the claimed polypeptide or pharmaceutical composition to treat all diseases associated with aberrant growth, migration, regeneration or proliferation of cells that express an

AMIGO receptor or to treat all forms of tumors related EGFR autophosphorylation since it is unknown what specific disease associated with aberrant growth, migration, regeneration or proliferation are and EGFR is also involved in regular neural development. Applicant fails to provide sufficient guidance as to what specific disease are associated with aberrant growth and also fails to define aberrant growth since both tumors and cell death could be considered aberrant growth. Since it is unclear what diseases would be characterized associated with aberrant growth, it is unpredictable whether all types of AMIGO polypeptides/peptides/fragments could be used to treat these unspecified diseases. In addition, although phosphorylation of EGFR have been shown to be involved in tumor development, EGF/EGFR activity is also essential for neural survival and development. Applicant fails to teach how to regulate the blocking activity of EGFR without affecting the normal activity of EGFR in normal neural development by administration of all polypeptides comprising all possible fragments of AMIGO that binds to an AMIGO receptor.

The specification fails to provide sufficient guidance as to practice the claimed pharmaceutical composition and polypeptides in treating any disease because it would require knowledge of the route, duration and quantity of administration of the claimed pharmaceutical composition and polypeptides to a subject and this information is not provided by the instant specification. The instant specification has also failed to disclose how these parameters are to be determined. In the absence of this guidance a practitioner would have to resort to a substantial amount of undue experimentation involving the variation in the

amount and duration of administration of an unknown compound of the instant invention and in determining a suitable route of administration.

In addition, Applicant fails to teach what specific regions/structures are required for an AMIGO polypeptide/peptide/fusion protein to have effects on treating all different diseases as recited in claim 20. There are no required common regions and there is no guidance as to what could be changed and what could not be changed to preserve any common characteristics or activity of the ectodomain of AMIGO in promoting neurite outgrowth. Applicant also fails to teach what specific amino acids/regions could be included/not included in a polypeptides comprising all possible AMIGO fragments to have the blocking activity of AMIGO in inhibiting EGFR or AMIGO receptor as in claim 58 and further to treat all diseases associated with aberrant growth, migration, regeneration, proliferation of cells that express an AMIGO receptor. There are no required common regions and there is no guidance as to what could be changed and what could not be changed to preserve any common characteristics or activity of the AMIGO fragments to block neurite outgrowth, migration, proliferation of cells expressing AMIGO receptors or EGR phosphorylation in cell proliferation or abnormal growth. The specification does not provide sufficient guidance of how to make and use these broad genera of AMIGO polypeptides/peptides/fragments.

Although Applicant defines homologs as polypeptides having sequences at least 45%-95% identical to the basic sequence and different substitutions on p. 30-31, the specification does not provide sufficient guidance as to what other

amino acids can be included/not included in the encoded polypeptides to maintain any structural or functional activity or specificity like SEQ ID NO:2. It has been shown that a single amino acid change can alter the function of a protein. For example, a substitution of lysine residue by glutamic acid at position 118 of acidic fibroblast growth factor results in a substantial loss of its biological activity including the binding ability to heparin and its receptor (Burgess et al. J of Cell Bio. 111:2129-2138, 1990). In addition, different homologs of receptors even binding to the same ligand may function differently, for example estrogen receptor. Both estrogen receptor- α and - β bind to estrogen and share highly homology (95% amino acid identity for DNA-binding domain and 55% amino acid identity for ligand-binding domain). However, estrogen receptor- β functions as a dominant negative molecule in cell proliferation whereas estrogen receptor- α functions in promoting cell proliferation (see Gustafsson, J. A.. Eur J Cancer. 2000 Sep;36 Suppl 4:S16). Furthermore, in addition to a core determinant sequence, the protein-protein interaction also relies on the flanking or noncontiguous residues (see p. 445 the second column, first paragraph, Pawson et al. 2003, Science 300:445-452). The optimal binding motif for a domain is not necessarily suitable for physiological or in vivo interaction. The predictive data always need to be validated by actual analyses in cells (see p. 445, the third column, second paragraph, Pawson et al. 2003, Science 300:445-452). Applicant fails to provide guidance as to what functional regions of the polypeptides are and what amino acid sequences are required in order to maintain a specific functional region. A skilled artisan cannot predict the function/activity of these

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claimed polypeptides. Thus, it is unpredictable whether the claimed polypeptides and pharmaceutical composition comprising the claimed polypeptides other than the full length of AMIGO could function as SEQ ID NO:2, indicating that undue experimentation is required to practice the claimed invention.

Therefore, the instant specification is not enabling for the claimed pharmaceutical composition as in claim 20 and polypeptides as in claim 58 because one can not follow the guidance presented therein and practice the claimed invention without first making a substantial inventive contribution. Therefore, in view of the necessity of experimentation, the limited working examples, the unpredictability of the art, and the lack of sufficient guidance in the specification and the lack of knowledge of function for each sequence, one of skill in the art would be required to perform undue experimentation in order to practice the claimed invention.

Claims 20 and 58 are also rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To provide adequate written description and evidence of possession of a claimed genus, the specification must provide sufficient distinguishing identifying characteristics of the genus. The factors to be considered include disclosure of complete or partial structure, physical and/or chemical properties, functional

characteristics, structure/function correlation, methods of making the claimed product, or any combination thereof.

Claim 20 is directed to a pharmaceutical composition comprising the AMIGO polypeptide/peptide/fusion protein. Claim 58 is directed to a polypeptide comprising a fragment of an AMIGO that binds to an AMIGO receptor for the treatment of disease characterized by aberrant growth, migration, regeneration or proliferation that express an AMIGO receptor. Claim 20 is drawn to a genus of AMIGO polypeptides/peptides. However, Applicant has not disclosed sufficient species for the broad genus of other polypeptides related to SEQ ID NO: 2 (AMIGO). Although claim 58 recite binding activity to an AMIGO receptor, Applicant fails to teach what specific common structures/characteristics of AMIGO fragments are responsible for binding activity. Thus, the claim encompasses a genus of polypeptides that are defined only by sequence similarity as in the specification. However, the instant specification fails to describe the entire genus of polypeptides comprising all AMIGO fragments or all polypeptides with limited homology to AMIGO that are encompassed by these claims. In making a determination of whether the application complies with the written description requirement of 35 U.S.C. 112, first paragraph, it is necessary to understand what Applicant is in possession of and what Applicant is claiming. From the specification, it is clear that Applicant is in possession of SEQ ID NO:2. However, the claims are not limited to the full-length polypeptides but also include fragments of AMIGO or peptides of AMIGO. The specification only describes the ectodomain of AMIGO but fails to teach or describe what specific

amino acids/structures that are required for the genus of AMIGO polypeptides/peptides or polypeptides comprising all AMIGO fragments in order to bind to an AMIGO receptor. There is no identification of what other particular portion of the AMIGO that must be conserved for polypeptides comprising all AMIGO fragments to bind to an AMIGO receptor. There is no indication what specific structures/amino acids must to be included or could/could not be changed in order to preserve the function of AMIGO. The instant specification fails to provide sufficient descriptive information, such as definitive structural features of the claimed genus of AMIGO polypeptides/peptides and the genus of polypeptides comprising all AMIGO fragments. There is no description of the conserved structures which are critical to the function of the genus claimed. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Furthermore, the prior art does not provide compensatory structural or correlative teachings sufficient to enable one of skill to isolate and identify all the polypeptides comprising all AMIGO fragments encompassed. Applicant fails to describes/specify what other common structures/characteristics that are required to preserve the function of SEQ ID NO:2 (AMIGO). Thus, a skilled artisan cannot contemplate the functional relationship between the above genera and the claimed invention.

Accordingly, in the absence of sufficient recitation of distinguishing identifying characteristics, the specification does not provide adequate written description of the genus of proteins used in the claimed methods.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the *invention*. The invention is, for purposes of the ‘written description’ inquiry, *whatever is now claimed.*” (See page 1117.) The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.” (See *Vas-Cath* at page 1116). As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF’s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, a pharmaceutical compound comprising an AMIGO polypeptide/peptide/fusion protein and a polypeptide comprising an AMIGO fragment that binds to a AMIGO receptor for treating diseases with aberrant growth have not met the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written

description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 7, 20 and 58 are rejected under 35 U.S.C. 102(b) as being anticipated by WO200070046 (published on Nov 23, 2000).

WO200070046 teaches SEQ ID NO:4, which has 100% identity to the instant SEQ ID NO:2. The intended use in treating diseases as recited in claims 20 and 58 are not given patentable weight since the claimed polypeptide does not result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the limitations of the claims. Therefore, Claims 7, 20 and 58 are anticipated by WO200070046. The sequence search results disclose as follows:

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AAB49650
ID AAB49650 standard; protein; 493 AA.
AC AAB49650;
DT 20-MAR-2001 (first entry)
DE Human SEC2 protein sequence SEQ ID 4.
KW SECX; secreted protein; cancer; angiogenesis; wound healing; immune disorder; neurodegenerative disease; allergic reaction; respiratory problem; organ transplantation; contraceptive; human; chromosome 1; proliferative disorder.
OS Homo sapiens.
PN WO2000070046-A2.
PD 23-NOV-2000.
PF 12-MAY-2000; 2000WO-US013291.
PR 14-MAY-1999; 99US-0134315P.
12-JAN-2000; 2000US-0175744P.
10-MAR-2000; 2000US-0188274P.
11-MAY-2000; 2000US-00569269.
PA (CURA-) CURAGEN CORP.
PI Shimkets RA, Fernandes E, Boldog F;
DR WPI; 2001-025020/03.
N-PSDB; AAF23411.
PT New SECX polypeptides and nucleic acids useful for treating or preventing cancer, other disorders related to angiogenesis, neurodegenerative diseases, autoimmune disorders and allergic reactions.
PS Claim 1; Page 12-14; 132pp; English.
CC Polynucleotide sequences AAF23410 - AAF23419 encode secreted SECX proteins AAB49649 - AAB49658. Sequences AAF23420 - AAF23450 represent primers and probes used in the isolation and characterisation of the SECX DNA sequences of the invention. The new polypeptides and nucleic acids can be used in screening assays, detection assays, preventive or predictive medicine, therapeutic and prophylactic treatment, and pharmacogenomics. Specifically, the SECX polypeptides and nucleic acids are useful for treating cancer; other disorders related to angiogenesis e.g. abnormal wound healing, psoriasis; neurodegenerative diseases; immune disorders; liver cirrhosis; benign tumours; fibrocystic conditions and tissue hypertrophy (e.g. benign prostatic hypertrophy); allergic reactions and conditions such as asthma and other respiratory problems; as well as in treating or preventing diseases associated with organ transplantation, atherosclerosis-associated diseases or disorders. The polypeptides can also be used for bone, cartilage, tendon, ligament and/or tissue growth or regeneration, wound healing, tissue repair and replacement, gut protection or regeneration, as a contraceptive, to inhibit thromboses, infections caused by bacteria, virus, fungi and other parasites, and as a vaccine. SECX antibodies may be used to isolate or detect SECX proteins, monitor protein level in tissue as part of a clinical testing procedure, treat proliferative disorders including tumours and benign hyperplasias
SQ Sequence 493 AA;
Query Match 100.0%; Score 2615; DB 4; Length 493;
Best Local Similarity 100.0%; Pred. No. 1e-223;
Matches 493; Conservative 0; Mismatches 0; Indels 0; Gaps 0
Qy 1 MPHHRDPRGLWLLLPSLSLLLFEVARAGRRAVVSCTPAACLCAASNLSCSKQQLPNVPHSLP 60
Db 1 MPHHRDPRGLWLLLPSLSLLLFEVARAGRRAVVSCTPAACLCAASNLSCSKQQLPNVPHSLP 60
Qy 61 SYTALLDLSSHNNLSRLRAEWTPTRLTLQHLSLLLSHHNLFISSEAFSPVNPRLYLDLSSN 120
Db 61 SYTALLDLSSHNNLSRLRAEWTPTRLTLQHLSLLLSHHNLFISSEAFSPVNPRLYLDLSSN 120
Qy 121 QLRTLDEFLFSDLQVLLEVLLLYNNHIMAVDRCAFDDMAQLQKLYLSQNQISRFPLELVKE 180
Db 121 QLRTLDEFLFSDLQVLLEVLLLYNNHIMAVDRCAFDDMAQLQKLYLSQNQISRFPLELVKE 180
Qy 181 GAKLPKLTLDDLSNSNKLKNLPLPDLKLPWIKNGLYLHNHNPNCDCELYQLQFSHWQYRQ 240
Db 181 GAKLPKLTLDDLSNSNKLKNLPLPDLKLPWIKNGLYLHNHNPNCDCELYQLQFSHWQYRQ 240
Qy 241 LSSVMDFQEDLYCMNSKKLHNVFNLSPLNCGEYKERAEWAHLGDTLIIKCDTKQQGMTKV 300
Db 241 LSSVMDFQEDLYCMNSKKLHNVFNLSPLNCGEYKERAEWAHLGDTLIIKCDTKQQGMTKV 300
Qy 301 WVTPSNERVLDEVNTGTVSVSKDGSLLFQOQVQVEDGGVTCYAMGETFNETLSELVKVHN 360
Db 301 WVTPSNERVLDEVNTGTVSVSKDGSLLFQOQVQVEDGGVTCYAMGETFNETLSELVKVHN 360
Qy 361 FT LHGHHD TLNTA YTT LVGCILS VV LVI LY LT PCRCW CRGV EKPSS HQGD SLS SMLS 420
Db 361 FT LHGHHD TLNTA YTT LVGCILS VV LVI LY LT PCRCW CRGV EKPSS HQGD SLS SMLS 420
Qy 421 TTPNHDPMAGGD KDDG FD RRR VAFLE PAG PGOGONGKL KPGNTL LPV PEAT GK QRRMS DPE 480
Db 421 TTPNHDPMAGGD KDDG FD RRR VAFLE PAG PGOGONGKL KPGNTL LPV PEAT GK QRRMS DPE 480
Qy 481 SVSSVFS DTDPIVV 493

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Db |||||||
 481 SVSSVFSDTPIVV 493

Conclusion

NO CLAIM IS ALLOWED.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

ABP68987
 ID ABP68987 standard; protein; 493 AA.
 AC ABP68987;
 DT 20-JAN-2003 (first entry)
 DE Human polypeptide SEQ ID NO 1034.
 KW Human; genome mapping; gene therapy; food supplement; virus; fungus; cell-proliferative disorder; neurodegenerative disease; bacterial; Parkinson's disease; Alzheimer's disease; autoimmune disease; multiple sclerosis; diabetes; genetic disorder; wound; burn; infection; arthritis; cytostatic; immunomodulator; nootropic; neuroprotective; antiparkinsonian; antidiabetic; immunosuppressive; dermatological; haemostatic; vulnerary; fungicide; antibacterial; virucide; protozoacide; antiarthritic.
 OS Homo sapiens.
 PN WO200270539-A2.
 PD 12-SEP-2002.
 PF 05-MAR-2002; 2002WO-US005095.
 PR 05-MAR-2001; 2001US-00799451.
 PA (HYSE-) HYSEQ INC.
 PI Tang YT, Zhou P, Goodrich RW, Asundi V, Zhang J, Zhao QA, Ren F; Xue AJ, Yang Y, Ma Y, Yamazaki V, Chen R, Wang Z, Ghosh M; Wehrman T, Wang J, Wang D, Drmanac RT;
 DR WPI; 2002-759812/82.
 N-PSDB; ABZ11204.
 PT New polynucleotides comprising sequences assembled from expressed sequence tags (ESTs), useful for treating cell-proliferative, neurodegenerative, autoimmune, genetic, myeloid or lymphoid, or platelet or coagulation disorders.
 PS Claim 9; SEQ ID NO 1034; 1012pp + Sequence Listing; English.
 CC The invention relates to an isolated polynucleotide (I) comprising a nucleotide sequence selected from any of 948 sequences (ABZ11119-ABZ12066) or their mature protein coding portion, active domain coding protein or complementary sequences. The polynucleotides are useful for identifying expressed genes or for physical mapping of human genome. The encoded polypeptides (ABP68902-ABP69849) are useful as molecular weight markers, as a food supplement, for generating antibodies, in medical imaging, screening and diagnostic assays and for treating cell-proliferative disorders (cancer), neurodegenerative diseases (Parkinson's or Alzheimer's disease), autoimmune diseases (multiple sclerosis, diabetes, lupus) genetic disorders, myeloid or lymphoid disorders, platelet or coagulation disorders, wound, burns, incision, ulcers, liver or lung fibrosis, infections (bacterial, viral, fungal, parasitic), arthritis, etc. Note: The sequence data for this patent did not form part of the printed specification, but was obtained in electronic format directly from WIPO at ftp://wipo.int/pub/published_pct_sequences
 SQ Sequence 493 AA;
 Query Match 100.0%; Score 2615; DB 5; Length 493;
 Best Local Similarity 100.0%; Pred. No. 1e-223;
 Matches 493; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
 Qy 1 MHPHRDPRLWLLLPSLSLLLFEVARAGRRAVVSCTPAACLCASNLSCSKQQLPNVPHSLP 60
 Db 1 MHPHRDPRLWLLLPSLSLLLFEVARAGRRAVVSCTPAACLCASNLSCSKQQLPNVPHSLP 60
 Qy 61 SYTALLDLHNNLRSRLRAEWTPTRLTQLHSLLLSHNHLNFISSEAFSPVPNLRYLDLSSN 120
 |||||||

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Db      61 SYTALLDLSHNNLRLRAEWTPTRLTQLHSLLLHNLNFISSAEFSPVPLRYLDLSSN 120
Qy      121 QLRTLDEFDSLQVLEVLLYNNHIMAVDRCAFDDMAQLQKLYLSQNQISRFPLELVKE 180
Db      121 QLRTLDEFDSLQVLEVLLYNNHIMAVDRCAFDDMAQLQKLYLSQNQISRFPLELVKE 180
Qy      181 GAKLPKLTLDDLSNKLKNLPLPDLQKLPWIKNGLYLHNPLNCDCELYQLFSHWQYRQ 240
Db      181 GAKLPKLTLDDLSNKLKNLPLPDLQKLPWIKNGLYLHNPLNCDCELYQLFSHWQYRQ 240
Qy      241 LSSVMDFQEDLYCMNSKKLHNVFNLSPFLNCGEYKERAEAHLDTLIICKDTKQQGMTKV 300
Db      241 LSSVMDFQEDLYCMNSKKLHNVFNLSPFLNCGEYKERAEAHLDTLIICKDTKQQGMTKV 300
Qy      301 WVTPSNERVLDEVTINGTVSVSKDGSLLFQQVQVEDGGVYTCYAMGETFNETLSVELKVN 360
Db      301 WVTPSNERVLDEVTINGTVSVSKDGSLLFQQVQVEDGGVYTCYAMGETFNETLSVELKVN 360
Qy      361 FTLGHGHDTLNTAYTTLVGCILSVVLVLIYLYLTPCRWCRCGVKEKPSSHQGDSLSSMLS 420
Db      361 FTLGHGHDTLNTAYTTLVGCILSVVLVLIYLYLTPCRWCRCGVKEKPSSHQGDSLSSMLS 420
Qy      421 TTPNHDPMAGGDKDGFDRRVAPLEPAGPGQGQNGKLKGNTLPVPEATGKGQRMSDPE 480
Db      421 TTPNHDPMAGGDKDGFDRRVAPLEPAGPGQGQNGKLKGNTLPVPEATGKGQRMSDPE 480
Qy      481 SVSSVFSDTPIVV 493
Db      481 SVSSVFSDTPIVV 493

```

ABJ10921

ID ABJ10921 standard; protein; 493 AA.
AC ABJ10921;
DT 05-DEC-2002 (first entry)
DE Human secreted protein (SECP) #17.
KW Human; gene therapy; secreted protein; SECP; hepatitis; cancer; cell proliferative disorder; autoimmune disorder; inflammatory disorder; AIDS; asthma; anaemia; allergy; atopic dermatitis; myocardial infarction; cardiovascular disorder; vascular tumour; neurological disorder; stroke; epilepsy; cerebral neoplasm; Alzheimer's disease; developmental disorder; Cushing's syndrome; muscular dystrophy.
OS Homo sapiens.
PN WO200270669-A2.
PD 12-SEP-2002.
PP 05-MAR-2002; 2002WO-US007719.
PR 06-MAR-2001; 2001US-0273946P.
16-MAR-2001; 2001US-0276873P.
30-MAR-2001; 2001US-0280531P.
30-MAR-2001; 2001US-0280596P.
16-NOV-2001; 2001US-0332426P.
28-NOV-2001; 2001US-0334229P.
11-JAN-2002; 2002US-0347703P.
PA (INCY-) INCYTE GENOMICS INC.
PI Yue H, Yang J, Elliott VS, Duggan BM, Honchell CD, Lee S; Thangavelu K, Gietzen KJ, Forsythe IJ, Lu DAM, Griffin JA; Gururajan R, Lal PG, Baughn MR, Xu Y, Tang YT, Azimzai Y; Au-Young J, Kallick DA, Walia NK, Mason PM, Tran UK; DR WPI; 2002-71344/77.
N-PSDB; ABT11195.
PT New human secreted proteins and nucleic acids useful in diagnosing, treating and preventing cell proliferative, autoimmune/inflammatory, cardiovascular, neurological, and developmental disorders.
PS Claim 1; Page 139-140; 162pp; English.
CC The invention comprises the amino acid and coding sequences of human secreted proteins (SECP). The human SECP DNA and protein sequences of the invention are useful for the treatment and prevention of cell proliferative disorders (e.g. actinic keratosis, arteriosclerosis, bursitis, hepatitis or cancer); autoimmune/inflammatory disorders (e.g. AIDS, asthma, anaemia, allergies or atopic dermatitis); cardiovascular disorders (e.g. congestive heart failure, ischaemic heart disease, myocardial infarction, hypertensive heart disease, or vascular tumours); neurological disorders (e.g. epilepsy, stroke, cerebral neoplasms, or Alzheimer's disease); and developmental disorders (e.g. renal tubular acidosis, Cushing's syndrome, Duchenne and Becker muscular dystrophy, or hypothyroidism). The present amino acid sequence represents a human secreted protein (SECP) of the invention
SQ Sequence 493 AA;

Query Match 100.0%; Score 2615; DB 5; Length 493;
Best Local Similarity 100.0%; Pred. No. 1e-223;
Matches 493; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

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Qy      1 MHPHRDPRGLWLLPSLSSLFEVARAGRAVVSCPAACLCASNILSCSKQQLPNVPHSLP 60
Db      1 MHPHRDPRGLWLLPSLSSLFEVARAGRAVVSCPAACLCASNILSCSKQQLPNVPHSLP 60

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Qy 61 SYTALLDLSHNNLRLRAEWTPTRLTQLHSLLLShNlnFISSEAFSPVPNLRYLDLSSN 120
 |||||
 Db 61 SYTALLDLSHNNLRLRAEWTPTRLTQLHSLLLShNlnFISSEAFSPVPNLRYLDLSSN 120
 Qy 121 QLRTLDEFLFSDLQVLEVLLYNNHIMAVDRCAFDDMAQLQKLYLSQNQISRFPLELVKE 180
 |||||
 Db 121 QLRTLDEFLFSDLQVLEVLLYNNHIMAVDRCAFDDMAQLQKLYLSQNQISRFPLELVKE 180
 Qy 181 GAKLPKLTLLDLSSNKLKNLPLPDLQKLPWIKNGLYLHNNPLNCDCELYQLFSHWQYRQ 240
 |||||
 Db 181 GAKLPKLTLLDLSSNKLKNLPLPDLQKLPWIKNGLYLHNNPLNCDCELYQLFSHWQYRQ 240
 Qy 241 LSSVMDPQEDLYCMNSKKLHNVFNLSPFLNCGEYKERAEAHLDGTLIICKCDTKQQGMTKV 300
 |||||
 Db 241 LSSVMDPQEDLYCMNSKKLHNVFNLSPFLNCGEYKERAEAHLDGTLIICKCDTKQQGMTKV 300
 Qy 301 WVTPSNERVLDEVNTGTVSVSKDGSLLFQQVQVEDGGVTCYAMGETFNETLSVELKVN 360
 |||||
 Db 301 WVTPSNERVLDEVNTGTVSVSKDGSLLFQQVQVEDGGVTCYAMGETFNETLSVELKVN 360
 Qy 361 FTLHGHHDTLNTAYTTLVGCILSVVVLVLYLTPCRCWCRGVKEPKSSHQGDSLSSMLS 420
 |||||
 Db 361 FTLHGHHDTLNTAYTTLVGCILSVVVLVLYLTPCRCWCRGVKEPKSSHQGDSLSSMLS 420
 Qy 421 TTPNHDPMAGGDKDGFDRRVAFLEPAGPGQGQNGKLKPGNTLPVPEATGKQRRMSDPE 480
 |||||
 Db 421 TTPNHDPMAGGDKDGFDRRVAFLEPAGPGQGQNGKLKPGNTLPVPEATGKQRRMSDPE 480
 Qy 481 SVSSVFSDTPIVV 493
 |||||
 Db 481 SVSSVFSDTPIVV 493

US-09-998-966-4

; Sequence 4, Application US/09998966
; Publication No. US20030194761A1
; GENERAL INFORMATION:
; APPLICANT: Shimkets, Richard
; APPLICANT: Fernandes, Elma
; APPLICANT: Boldog, Ferenc
; TITLE OF INVENTION: NOVEL POLYNUCLEOTIDES AND POLYPEPTIDES ENCODED THEREBY
; FILE REFERENCE: 15966-551
; CURRENT APPLICATION NUMBER: US/09/998,966
; CURRENT FILING DATE: 2001-10-31
; PRIOR APPLICATION NUMBER: 09/569,269
; PRIOR FILING DATE: 2000-05-11
; PRIOR APPLICATION NUMBER: 60/134,315
; PRIOR FILING DATE: 1999-05-14
; PRIOR APPLICATION NUMBER: 60/175,744
; PRIOR FILING DATE: 2000-01-12
; PRIOR APPLICATION NUMBER: 60/188,274
; PRIOR FILING DATE: 2000-03-10
; NUMBER OF SEQ ID NOS: 52
; SOFTWARE: PatentIn Ver. 2.0
; SEQ ID NO: 4
; LENGTH: 493
; TYPE: PRT
; ORGANISM: Homo sapiens

US-09-998-966-4

Query Match 100.0%; Score 2615; DB 3; Length 493;
 Best Local Similarity 100.0%; Pred. No. 1.5e-214;
 Matches 493; Conservative 0; Mismatches 0; Indels 0; Gaps 0;

Qy 1 MHPHRDPRLWLPSLSSLFEVARAGRIVVSCPAACLCASNILSCSKQQLPNVPHSLP 60
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 Db 1 MHPHRDPRLWLPSLSSLFEVARAGRIVVSCPAACLCASNILSCSKQQLPNVPHSLP 60
 Qy 61 SYTALLDLSHNNLRLRAEWTPTRLTQLHSLLLShNlnFISSEAFSPVPNLRYLDLSSN 120
 |||||
 Db 61 SYTALLDLSHNNLRLRAEWTPTRLTQLHSLLLShNlnFISSEAFSPVPNLRYLDLSSN 120
 Qy 121 QLRTLDEFLFSDLQVLEVLLYNNHIMAVDRCAFDDMAQLQKLYLSQNQISRFPLELVKE 180
 |||||
 Db 121 QLRTLDEFLFSDLQVLEVLLYNNHIMAVDRCAFDDMAQLQKLYLSQNQISRFPLELVKE 180
 Qy 181 GAKLPKLTLLDLSSNKLKNLPLPDLQKLPWIKNGLYLHNNPLNCDCELYQLFSHWQYRQ 240
 |||||
 Db 181 GAKLPKLTLLDLSSNKLKNLPLPDLQKLPWIKNGLYLHNNPLNCDCELYQLFSHWQYRQ 240
 Qy 241 LSSVMDPQEDLYCMNSKKLHNVFNLSPFLNCGEYKERAEAHLDGTLIICKCDTKQQGMTKV 300
 |||||
 Db 241 LSSVMDPQEDLYCMNSKKLHNVFNLSPFLNCGEYKERAEAHLDGTLIICKCDTKQQGMTKV 300
 Qy 301 WVTPSNERVLDEVNTGTVSVSKDGSLLFQQVQVEDGGVTCYAMGETFNETLSVELKVN 360

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Db      301 WVTSPSNERVLDEVTNGTJSVSKDGSLLFQQVQVEDGGVYTCYAMGETFNETLSVELKVHN 360
Qy      361 FTLHGHHDTLNTAYTTLVGCILSVVVLVLYLTPCRWCRGVEKPSSHQGDSLSSSMLS 420
Db      361 FTLHGHHDTLNTAYTTLVGCILSVVVLVLYLTPCRWCRGVEKPSSHQGDSLSSSMLS 420
Qy      421 TTPNHDPMAGGDKDDGFDRRAFLPAGPGQGQNGKLKGNTLPVPEATGKGQRMSDPE 480
Db      421 TTPNHDPMAGGDKDDGFDRRAFLPAGPGQGQNGKLKGNTLPVPEATGKGQRMSDPE 480
Qy      481 SVSSVFSDTPIVV 493
Db      481 SVSSVFSDTPIVV 493

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US-10-004-415-4

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; Sequence 4, Application US/10004415
; Publication No. US20030119095A1
; GENERAL INFORMATION:
; APPLICANT: Shimkets, Richard
; APPLICANT: Fernandes, Elma
; APPLICANT: Boldog, Ferenc
; TITLE OF INVENTION: NOVEL POLYNUCLEOTIDES AND POLYPEPTIDES ENCODED
; TITLE OF INVENTION: THEREBY
; FILE REFERENCE: 15966-551
; CURRENT APPLICATION NUMBER: US/10/004,415
; CURRENT FILING DATE: 2001-10-31
; PRIOR APPLICATION NUMBER: 09/569,269
; PRIOR FILING DATE: 2000-05-11
; PRIOR APPLICATION NUMBER: 60/134,315
; PRIOR FILING DATE: 1999-05-14
; PRIOR APPLICATION NUMBER: 60/175,744
; PRIOR FILING DATE: 2000-01-12
; PRIOR APPLICATION NUMBER: 60/188,274
; PRIOR FILING DATE: 2000-03-10
; NUMBER OF SEQ ID NOS: 52
; SOFTWARE: PatentIn Ver. 2.0
; SEQ ID NO 4
; LENGTH: 493
; TYPE: PRT
; ORGANISM: Homo sapiens
US-10-004-415-4

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Query Match      100.0%; Score 2615; DB 4; Length 493;
Best Local Similarity 100.0%; Pred. No. 1.5e-214;
Matches 493; Conservative 0; Mismatches 0; Indels 0; Gaps 0;
Qy      1 MHPHRDPRGLWLLPSLSSLFEVARAGRAVVSCPAACLCASNILSCSKQQLPNVPHSLP 60
Db      1 MHPHRDPRGLWLLPSLSSLFEVARAGRAVVSCPAACLCASNILSCSKQQLPNVPHSLP 60
Qy      61 SYTALLDLSHNNLRLRAEWTPTRLTQLHSLLLShnlnfisseeafspvpnlryldlssn 120
Db      61 SYTALLDLSHNNLRLRAEWTPTRLTQLHSLLLShnlnfisseeafspvpnlryldlssn 120
Qy      121 QLRTLDEFPLSDLQVLEVLLLYNNHIMAVDRCAFDDMAQLQKLYLSQNQISRFPLELVKE 180
Db      121 QLRTLDEFPLSDLQVLEVLLLYNNHIMAVDRCAFDDMAQLQKLYLSQNQISRFPLELVKE 180
Qy      181 GAKLPKLTLLDLSNNKLKNLPLPDLQKLPWKNGLYLHNNPLNCDCELYQLFSHWQYRQ 240
Db      181 GAKLPKLTLLDLSNNKLKNLPLPDLQKLPWKNGLYLHNNPLNCDCELYQLFSHWQYRQ 240
Qy      241 LSSVMDPQEDLYCMNSKKLHNVFNLNSFLNCGEYKERAWEAHLGDTLIIKCDTKQQGMTKV 300
Db      241 LSSVMDPQEDLYCMNSKKLHNVFNLNSFLNCGEYKERAWEAHLGDTLIIKCDTKQQGMTKV 300
Qy      301 WVTSPSNERVLDEVTNGTJSVSKDGSLLFQQVQVEDGGVYTCYAMGETFNETLSVELKVHN 360
Db      301 WVTSPSNERVLDEVTNGTJSVSKDGSLLFQQVQVEDGGVYTCYAMGETFNETLSVELKVHN 360
Qy      361 FTLHGHHDTLNTAYTTLVGCILSVVVLVLYLTPCRWCRGVEKPSSHQGDSLSSSMLS 420
Db      361 FTLHGHHDTLNTAYTTLVGCILSVVVLVLYLTPCRWCRGVEKPSSHQGDSLSSSMLS 420
Qy      421 TTPNHDPMAGGDKDDGFDRRAFLPAGPGQGQNGKLKGNTLPVPEATGKGQRMSDPE 480
Db      421 TTPNHDPMAGGDKDDGFDRRAFLPAGPGQGQNGKLKGNTLPVPEATGKGQRMSDPE 480
Qy      481 SVSSVFSDTPIVV 493
Db      481 SVSSVFSDTPIVV 493

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US-10-384-974-4

Art Unit: 1649

; Sequence 4, Application US/10384974
; Publication No. US20040014173A1
; GENERAL INFORMATION:
; APPLICANT: Anderson et al.
; TITLE OF INVENTION: No. US20040014173A1el Polynucleotides, Polypeptides Encoded Thereby
; TITLE OF INVENTION: and Methods of Use Thereof
; FILE REFERENCE: 15966-551C1P1CON1
; CURRENT APPLICATION NUMBER: US/10/384,974
; CURRENT FILING DATE: 2003-03-10
; PRIOR APPLICATION NUMBER: 10/081,407,
; PRIOR FILING DATE: 2000-05-11
; PRIOR APPLICATION NUMBER: 60/134,315
; PRIOR FILING DATE: 1999-05-14
; PRIOR APPLICATION NUMBER: 60/175,744
; PRIOR FILING DATE: 2000-01-12
; PRIOR APPLICATION NUMBER: 60/188,274
; PRIOR FILING DATE: 2000-03-10
; NUMBER OF SEQ ID NOS: 179
; SOFTWARE: CuraSeqList version 0.1
; SEQ ID NO 4
; LENGTH: 493
; TYPE: PRT
; ORGANISM: Homo sapiens
US-10-384-974-4

US-10-471-115-17
; Sequence 17, Application US/10471115
; Publication No. US20040101882A1
; GENERAL INFORMATION:
; APPLICANT: YUE, Henry; YANG, Junming;
; APPLICANT: ELLIOTT, Vicki S.; DUGGAN, Brendan M.;
; APPLICANT: HONCHELL, Cynthia D.; LEE, Sally;
; APPLICANT: THANGAVELU, Kavitha; GIETZEN, Kimberly J.;
; APPLICANT: FORSYTHE, Ian J.; LU, Dyung Aina M.;
; APPLICANT: GRIFFIN, Jennifer A.; GURURAJAN, Rajagopal;
; APPLICANT: LAL, Preeti G.; BAUGHN, Mariah R.;
; APPLICANT: XU, Yuming; TANG, Y. Tom;
; APPLICANT: AZIMZAI, Yalda; AU-YOUNG, Janice;
; APPLICANT: KALLICK, Deborah A.; CHAWLA, Narinder K.;
; APPLICANT: MASON, Patricia M.; TRAN, Uyen K.
; TITLE OF INVENTION: SECRETED PROTEINS
; FILE REFERENCE: PI-0394 USN
; CURRENT APPLICATION NUMBER: US/10/471,115
; CURRENT FILING DATE: 2003-09-05
; PRIOR APPLICATION NUMBER: PCT/US02/07719

Art Unit: 1649

Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers relating to this application may be submitted to Technology Center 1600, Group 1649 by facsimile transmission. The faxing of such papers must

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conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chang-Yu Wang, Ph.D. whose telephone number is (571) 272-4521. The examiner can normally be reached on Monday-Thursday and every other Friday from 8:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, Ph.D., can be reached at (571) 272-0867.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CYW
March 19, 2007



JANET L. ANDRES
SUPERVISORY PATENT EXAMINER